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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/086,427	06/29/93	GOSPODAROWICZ	D 0953.001
18N2/0726			KEMMERER EXAMINER
AMY L. COLLINS CHIRON CORP. 4560 HORTON ST. EMERYVILLE, CA 94608			ART UNIT PAPER NUMBER 1812 8

DATE MAILED: 07/26/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 25 APRIL 1994 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire THREE month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-23 are pending in the application.
Of the above, claims 5-8 AND 10-23 REMAIN are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-4 AND 9 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____ Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

08/086427
PTOL-328 (Rev. 2/93)

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EXAMINER'S ACTION

Applicant's election without traverse of Invention I (claims 1-4 and 9) in Paper No. 7 (25 April 1994) is acknowledged. Claims 5-8 and 10-23 remain withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, as set forth at p. 5 of the previous Office Action (Paper No. 5, 19 October 1993).

The requirement to review the application for typographical and grammatical errors as set forth at p. 5 of the previous Office Action (Paper No. 5, 19 October 1993) is maintained. Although Applicant has corrected the missing ATCC Accession numbers in the amendment filed 25 April 1994 (Paper No. 7), the incorrect referral to Fig. 4 as Fig. 5 remains at p. 38, line 22. This and any other clerical errors should be corrected, provided that doing so does not enter new matter into the specification.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification remains objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure, as

set forth at pp. 5-6 of the previous Office Action (Paper No. 5, 19 October 1993).

Claim 4 remains rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Applicant argues (pp. 2-3, Paper No. 7, 25 April 1994) that the specification teaches how to make KGF_{des1-23} at p. 11, lines 5-8 and lines 19-29 continuing to p. 12, lines 1-22. Applicant also urges that this molecule inherently possesses the property of decreased cytotoxicity as taught at p. 15, lines 7-13; p. 37, lines 3-5; and Fig. 4. Finally, Applicant argues that the potential uses of KGF_{des1-23} in wound healing and treatment of hyperproliferative disease of the epidermis have been taught, thus establishing the decreased cytotoxicity of the molecule. Applicant's arguments have been fully considered but are not deemed to be persuasive.

Claim 4 is not limited to KGF_{des1-23}; thus, arguments pertaining only to KGF_{des1-23} are not persuasive to establish enablement for the entire scope of the claims. However, the arguments will be addressed in the anticipation of Applicant choosing to limit future claims to KGF_{des1-23}. Although the specification may teach how to make KGF_{des1-23}, there is no evidence that the KGF_{des1-23} possesses decreased cytotoxicity, as required by the claim. Applicant points to p. 15, lines 7-13; p. 37, lines 3-5; and Fig. 4 as evidence of decreased cytotoxicity.

At p. 15, there is no indication that the difference in toxic effects between $\text{KGF}_{\text{des1-23}}$ and KGF_{163} is statistically significant. There is also no indication of sample size or controls, information which the skilled artisan would require in order to use the invention. At p. 37, only the bioactivity is discussed. There is no mention of cytotoxicity. Similarly, bioactivity is only demonstrated in Fig. 4, and pointed out in the Brief Description of Fig. 4. Applicant has not indicated exactly which data presented in Fig. 4 speak to decreased cytotoxicity.

Claims 1-3 and 9 remain rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to $\text{KGF}_{\text{des1-23}}$ as set forth at pp. 6-7 of the previous Office Action (Paper No. 5, 19 October 1993). See M.P.E.P. §§ 706.03(n) and 706.03(z).

Applicant argues (pp. 3-4, Paper No. 7, 25 April 1994) that the specification defines and teaches how to make and use the claimed KGF analogs at p. 6, lines 10-18 and p. 6, line 9 to p. 7, line 7. Applicant further urges that amino acid substitutions, deletions, or substitutions were within the skill of persons in the art and that some experimentation is not detrimental to enablement. Applicant's arguments have been fully considered but are not deemed to be persuasive *for the breadth of the claims for fragments, analogs or portions of KGF.*

The indicated portions of the specification speak mostly to $\text{KGF}_{\text{des1-23}}$, which is what the claims are being limited to in the

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instant scope-limiting rejection under 35 U.S.C. § 112, first paragraph. However, the indicated portions of the specification also mention amino acid substitutions, deletions, or insertions. Although making KGF analogs with substitutions, deletions, and insertions per se may be within the skill of the person in the art, there is no reasonable expectation that such analogs would have the required activity recited in the claims. The specification provides only a single working example: KGF_{des1-23}. As was found in Ex parte Hitzeman, 9 USPQ2d 1821, a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE

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STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

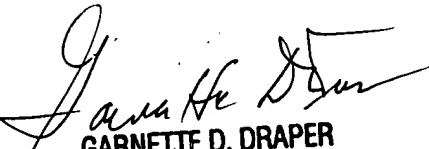
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Elizabeth C. Kemmerer, whose telephone number is (703) 308-2673. The Examiner can normally be reached on Tuesdays through Fridays from 7:30 a.m. to 5:00 p.m. The Examiner can also be reached on alternate Mondays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Ms. Garnette D. Draper, can be reached on (703) 308-4232. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

CEK

Elizabeth C. Kemmerer, Ph.D.
July 12, 1994


GARNETTE D. DRAPER
SUPERVISORY PATENT EXAMINER
GROUP 1800